Complete Summary

GUIDELINE TITLE

Fibromyalgia.

BIBLIOGRAPHIC SOURCE(S)

Fibromyalgia. Philadelphia (PA): Intracorp; 2004. Various p.

GUIDELINE STATUS

This is the current release of the guideline.

All Intracorp guidelines are reviewed annually and updated as necessary, but no less frequently than every 2 years. This guideline is effective from January 1, 2004 to January 1, 2006.

** REGULATORY ALERT **

FDA WARNING/REGULATORY ALERT

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory information has been released.

On April 7, 2005, after concluding that the overall risk versus benefit profile is unfavorable, the FDA requested that Pfizer, Inc voluntarily withdraw Bextra (valdecoxib) from the market. The FDA also asked manufacturers of all marketed prescription nonsteroidal anti-inflammatory drugs (NSAIDs), including Celebrex (celecoxib), a COX-2 selective NSAID, to revise the labeling (package insert) for their products to include a boxed warning and a Medication Guide. Finally, FDA asked manufacturers of non-prescription (over the counter [OTC]) NSAIDs to revise their labeling to include more specific information about the potential gastrointestinal (GI) and cardiovascular (CV) risks, and information to assist consumers in the safe use of the drug. See the FDA Web site for more information.

Subsequently, on June 15, 2005, the FDA requested that sponsors of all non-steroidal anti-inflammatory drugs (NSAID) make labeling changes to their products. FDA recommended proposed labeling for both the prescription and over-the-counter (OTC) NSAIDs and a medication guide for the entire class of prescription products. All sponsors of marketed prescription NSAIDs, including Celebrex (celecoxib), a COX-2 selective NSAID, have been asked to revise the labeling (package insert) for their products to include a boxed warning, highlighting the potential for increased risk of cardiovascular (CV) events and the well described, serious, potential life-threatening gastrointestinal (GI) bleeding associated with their use. FDA regulation 21CFR 208 requires a Medication Guide

to be provided with each prescription that is dispensed for products that FDA determines pose a serious and significant public health concern. See the FDA Web site for more information.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Fibromyalgia

GUIDELINE CATEGORY

Diagnosis
Evaluation
Management
Treatment

CLINICAL SPECIALTY

Chiropractic
Family Practice
Internal Medicine
Rheumatology

INTENDED USERS

Allied Health Personnel
Health Care Providers
Health Plans
Hospitals
Managed Care Organizations
Utilization Management

GUIDELINE OBJECTIVE(S)

To present recommendations for the diagnosis, treatment, and management of fibromyalgia that will assist medical management leaders to make appropriate benefit coverage determinations

TARGET POPULATION

Individuals with fibromyalgia

INTERVENTIONS AND PRACTICES CONSIDERED

Diagnosis/Evaluation

1. Physical examination and assessment of signs and symptoms
2. Diagnostic tests
    - Erythrocyte sedimentation rate (ESR)
    - Thyroid stimulating hormone level (TSH)

Treatment/Management

1. Medication
    - Antidepressants and muscle relaxants
    - Acetaminophen with tramadol (Ultracet)
    - Aspirin, Advil, Motrin
    - Amitriptyline, cyclobenzaprine
    - Local anesthetic injection
2. Heat to tender areas and gentle massage
3. Gradual exercise program
4. Education and support
5. Specialist consultation
6. Psychotherapy
7. Manipulation and acupuncture

Note: Narcotics and corticosteroids are not recommended

MAJOR OUTCOMES CONSIDERED

Not stated

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Searches were performed of the following resources: reviews by independent medical technology assessment vendors (such as the Cochrane Library, HAYES);

PubMed; MD Consult; the Centers for Disease Control and Prevention (CDC); the U.S. Food and Drug Administration (FDA); professional society position statements and recommended guidelines; peer reviewed medical and technology publications and journals; medical journals by specialty; National Library of Medicine; Agency for Healthcare Research and Quality; Centers for Medicare and Medicaid Services; and Federal and State Jurisdictional mandates.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Not Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not stated

METHODS USED TO ANALYZE THE EVIDENCE

Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus (Delphi)

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

A draft Clinical Resource Tool (CRT or guideline) is prepared by a primary researcher and presented to the Medical Technology Assessment Committee or the Intracorp Guideline Quality Committee, dependent upon guideline product type.

The Medical Technology Assessment Committee is the governing body for the assessment of emerging and evolving technology. This Committee is comprised of a Medical Technology Assessment Medical Director, the Benefit and Coverage Medical Director, CIGNA Pharmacy, physicians from across the enterprise, the Clinical Resource Unit staff, Legal Department, Operations, and Quality. The Intracorp Guideline Quality Committee is similarly staffed by Senior and Associate Disability Medical Directors.

Revisions are suggested and considered. A vote is taken for acceptance or denial of the CRT.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Comparison with Guidelines from Other Groups
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Not stated

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Diagnostic Confirmation

Subjective Findings

- Criteria for the diagnosis of fibromyalgia require that 5 of the 8 subjective findings and all of the objective findings be met:
    - Sleep disturbance
    - Fatigue
    - Morning stiffness
    - Headaches
    - Swelling or numbness of upper and lower extremities
    - Raynaud's-like symptoms (entire hand turning pale or red)
    - Irritable bowel
    - Bladder spasms
    - Multifocal pain

Objective Findings

- Severe, aching pain of at least 3 months duration that is above and below the waist and on both left and right sides of the body
- Pain in 11 of 18 tender point sites on digital palpation (see figure in the original guideline document)
    - Bilateral occiput at muscle insertions
    - Low cervical (C5-C7)
    - Trapezius (bilateral) at upper border
    - Supraspinatus bilateral
    - 2nd rib bilateral at costochondral junction
    - Bilateral lateral epicondyle

- Gluteal bilateral
- Greater trochanter bilateral
- Bilateral knee (medially)

Diagnostic Tests

- Thorough physical exam
- Laboratory tests: Erythrocyte sedimentation rate (ESR), thyroid stimulating hormone level (TSH) to rule out potential differential diagnoses

Differential Diagnosis

- Most common other conditions:
  - Polymyalgia rheumatica
  - Hypothyroidism
  - Osteoarthritis (see the Intracorp Arthritis guidelines)
  - Prodromal phase of a connective tissue disease
  - Sjogren's syndrome
  - Bursitis/tendinitis
- Least common other conditions:
  - Osteopenia/osteomalacia (see the Intracorp guideline Avascular Necrosis)
  - Metabolic myopathy
  - Acromegaly
  - Hyperparathyroidism
  - Parkinson´s disease
  - Lupus

Treatment Options

- ALWAYS RECOMMENDED
  - Exercise program – gradual
  - Education
  - Support
- RECOMMENDED
  - Low-dose antidepressants, muscle relaxants
  - Acetaminophen in combination with tramadol (Ultracet)
  - Analgesics (aspirin) or modest doses of nonsteroidal anti-inflammatory drugs (NSAID) (e.g., Advil, Motrin)
  - Heat to the tender areas and gentle massage
- FAILURE TO PROGRESS
  - Consultation with psychiatrist, physiatrist, psychopharmacologist, sleep laboratory
  - Medication to improve sleep: amitriptyline, cyclobenzaprine
  - Injections of local anesthetic
  - Intensive pain management
  - Psychotherapy
  - Manipulation
  - Acupuncture
- TREATMENTS NOT RECOMMENDED
  - Narcotics
  - Corticosteroids

Duration of Medical Treatment

- Medical - optimal: 28 days; maximal: 360 days

Additional provider information regarding primary care visit schedules, referral options, frequency and duration of specialty care, physical therapy, and chiropractic treatment is provided in the original guideline document.

The original guideline document also provides a list of red flags that may affect disability duration, and return to work goals, including

- Resolving pain and stiffness
- Resolving sleep disturbances
- Resolving fatigue
- Resolving bowel and bladder symptoms

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

To date there are no randomized controlled trials on which to base any diagnostic and treatment guidelines. Therefore, recommendations in this guideline are derived from a synthesis of the literature and consensus of opinion among experts and practicing clinicians.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate diagnosis, treatment, and management of fibromyalgia that assist medical management leaders in making appropriate benefit coverage determinations

POTENTIAL HARMS

Not stated

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

To date, there are no randomized controlled trials on which to base any diagnostic and treatment guidelines.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Living with Illness

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Fibromyalgia. Philadelphia (PA): Intracorp; 2004. Various p.

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

1997 (revised 2004)

GUIDELINE DEVELOPER(S)

Intracorp - Public For Profit Organization

SOURCE(S) OF FUNDING

Intracorp

GUIDELINE COMMITTEE

CIGNA Clinical Resources Unit (CRU)
Intracorp Disability Clinical Advisory Team (DCAT)
Medical Technology Assessment Committee (MTAC)
Intracorp Guideline Quality Committee

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Not stated

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

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AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

- Policies and procedures. Medical Technology Assessment Committee Review Process. Philadelphia (PA): Intracorp; 2004. 4 p.

Licensing information and pricing: Available from Intracorp, 1601 Chestnut Street, TL-09C, Philadelphia, PA 19192; e-mail: lbowman@mail.intracorp.com.

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI on November 24, 2004. The information was verified by the guideline developer on December 8, 2004. This summary was updated on May 3, 2005 following the withdrawal of Bextra (valdecoxib) from the market and the release of heightened warnings for Celebrex (celecoxib) and other nonselective nonsteroidal anti-inflammatory drugs (NSAIDs). This summary was updated by ECRI on June 16, 2005, following the U.S. Food and Drug Administration advisory on COX-2 selective and non-selective non-steroidal anti-inflammatory drugs (NSAIDS).

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